UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,152	01/31/2002	Shuji Saitoh	020058	5985

23850 7590 06/17/2003

ARMSTRONG,WESTERMAN & HATTORI, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/059,152	Saitoh et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 23, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *8*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment B, paper No. 7, filed 05/23/2003. Claims 1-6 are pending. Claims 1, and 2 have been amended. Claims 1-6 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note any grounds of rejection that has not been repeated is removed.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 2/27/2003. Applicants argue that further limitation on location of the F gene is not necessary for the claim to be indefinite. In addition, applicants assert "This affects the dependent claims" is unclear, because non of the dependent claims mentions the term "essential regions", applicants conclude claim 1 is not indefinite.

Regarding the claim 2, Applicants assert that the specification cites several inter-Orf region on page 6 last paragraph.

Regarding the claim 4 Applicants assert that the "antigen" of avian herpesvirus is not needed to define the claimed invention. In addition, applicants assert that "avian herpesvirus antigens" are

not even recited in the claims. Applicants assert that there is no requirement that the inventor of an invention even know the exact mechanism by which this invention works. Applicants argue that the claims are definite. Applicant's argument as part of amendment B, Paper NO. 7, filed 5/23/03 has been considered fully, but they are not persuasive. At the onset applicants are reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Conterrey to applicants' assertion the specific region for the insertion of a heterologous gene is extremely important since the viability of the virus depends on the insertion region. The claim should clearly state where the foreign gene is to be placed. In addition, since the claims depend on the main claim 1, when the main claim is rejected the claims that depend from claim 1 are also rejected. Hence, "This affects the dependent claims", is added. Regarding Claim 2, the specification on page 6 refers to UL43, US2, and only inter-ORF region between UL44 and UL46. The UL43, and US2 are not inter-ORF regions, hence, the intended metes and bounds of the region is not defined. In addition, the limitations from the specification is not read into the claim. As for claim 4, applicants are requested to read their own claim. The claim specifically states that "protective immunity" is induced in an avian host against "avian herpesvirus and Newcastle disease virus" , the protective response is induced by the host against the antigen (emphasis added), how else the response is directed? Since, the specific antigens are not recited the claim is indeed indefinite. Still further, the Office did not ask for mechanism of action under this statute, how ever, the claim is reciting "protective immunity" which is an action taht is

suppose to be proformed by the methdo, and one should be appraise of what the elemnts are in the methdo whcih are supose to induce "protective immunity", and that is what the Office asked. The claims should be clear and distinctive to the subject matter applicants regard their invention. This is not the case, the claims are not clear since the boundaries of the claim invention is vague. The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 2/27/2003. Applicants argue the specification is clearly indicating that the general method of generating recombinant avian herpesvirus are known in the art, applicants assert that the "unpredictability" is not an issue with respect to enablement of the present claims. Regarding the polyvalent vaccine, applicants assert that they are not sure whether Office refers to making or using a polyvalent vaccine. Applicants assert that the specification teaches how to inoculate chickens. Applicants add that no undue experimentation would be required that is effective against both avian herpesvirus and Newcastle disease virus. Still further, applicants assert that the vector backbone acting as an antigen are not relevant. Applicants assert the mechanisms of action of vaccine is not an issue, as long as one of skill in the art can follow the method disclosed in the specification and obtain a recombinant herpesvirus as claimed, the claims are enabled. Applicant's argument as part of amendment B, Paper NO. 7, filed 5/23/03 has been considered fully, but they are not persuasive. Firs, the Unpredictability is

very important under this statute (emphasis added). Unpredictability, is a corner stone of enablement see In re Wand. Applicants are the ones asking for patent protection and cannot ask others to enable their invention where because of unpredictability of the field, undue experimentation would be required to enable the full scope of the claimed invention. The specification on page 4 states that the objective was not easily attainable and refers to Morgen et al (see page 4, of the specification), this is the crux of unpredictability of the field which those skilled in the art have not being able to work-out. The only reason applicants have observed the results is because of the insertion of F gene in between UL44 and 45 as taught by Saitoh et al, and because of the promoter defined by SEQ ID NO: 1. However, the scope of the claims are not reflective within the scope of teaching provided in the specification. As it was articulated by the Office the disclosure does not provide adequate teaching for all regions where a suitable insertion of F gene of NDV can be inserted. If suitable region(s) is/are not taught the vector maybe ineffective since it may become disabled and no expression would take place. In addition, not all non- essential regions are identified where a successful insertion can be made. Absent teaching undue experimentation would be required of one of ordinary skill in the art to enable the claimed invention. Applicants do not provide argument for these issues raised, and simply dismiss it as routine in the art. If the vector is not able to express the gene, then it's useless, and it is important to know where the gene is inserted (emphasis added). Moreover, with regard to a polyvalent vaccine, the backbone is very important, if the antigen of the backbones are the intended antigens then the immune response would be directed against the backbone which would be digested. How

can this point not be important? If the claimed invention is directed to a polyvalent vaccine and the specification doe not provide adequate teaching for that vaccine, then why should applicants be the ones to receive the exclusive patent protection for the polyvalent vaccine? The antigens of the vector that are suppose to participate as polyvalent vaccine are important, since if the no-structural antigen is targeted no effective protection would be observed, which absent teaching undue experimentation would be required. Therefore, since the specification does not provide adequate teaching for a method of polyvalent vaccine undue experimentation would be required to enable the full scope of the invention. Applicants cannot rely on others to enable the broad scope of their claimed invention absent adequate teaching. Still further, applicants assertion that mechanisms of action is not an issue is respectfully noted, however, if the claimed invention is directed to a certain mechanism of action, such as induction of protection, then the specification should provide how one can make and use the invention absent undue experimentation as was clearly previously articulated under the 112, 1st paragraph. Moreover, if applicants are requesting for broad protection, then they should provide adequate teaching so others would not be forced into undue experimentation. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*. The rejection is respectfully maintained.

No Claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A.R. Salimi

6/16/2003